VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Braftovi Prior Authorization Policy
- Braftovi® (encorafenib capsules – Array BioPharma)

REVIEW DATE: 07/19/2023; selected revision 10/18/2023

OVERVIEW

Braftovi, a BRAF inhibitor, is indicated for the following uses:[1]

- **Colorectal cancer**, in combination with Erbitux® (cetuximab intravenous infusion), for the treatment of metastatic disease and a *BRAF V600E* mutation, as detected by an FDA-approved test, after prior therapy in adults.
- **Melanoma**, in combination with Mektovi® (binimetinib tablets), for the treatment of unresectable or metastatic disease and a *BRAF V600E* or *V600K* mutation, as detected by an FDA-approved test in adults.
- **Non-small cell lung cancer (NSCLC),** in combination with Mektovi, for the treatment of adult patients with metastatic NSCLC with a *BRAF V600E* mutation, as detected by an FDA-approved test.

It is a limitation of use that Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF colorectal cancer, or wild-type BRAF NSCLC.

Guidelines

National Comprehensive Cancer Network guidelines support use of Braftovi in the following cancers.[5]

- **Colon** and **Rectal Cancer:** Guidelines for colon cancer (version 2.2023 – April 25, 2023) and rectal cancer (version 3.2023 – March 26, 2023) recommend Braftovi for some situations in patients with *BRAF V600E*-mutated disease.[3] For primary treatment (following adjuvant chemotherapy) or as subsequent use, Braftovi + Erbitux or Vectibix® (panitumumab intravenous infusion) is a recommended treatment option.
- **Melanoma, Cutaneous:** Guidelines (version 2.2023 – March 10, 2023) recommend BRAF/MEK inhibitor combinations among the preferred therapies for first-line and subsequent treatment of metastatic or unresectable melanoma with a *V600*-activating mutation.[2] The combinations are also recommended for adjuvant treatment (category 2B). While combination BRAF/MEK inhibition is preferred, if a combination is contraindicated, monotherapy with a BRAF inhibitor (Tafinlar® [dabrafenib capsules] or Zelboraf® [vemurafenib tablets]) is a recommended option, especially in patients who are not appropriate candidates for checkpoint immunotherapy.
- **Non-Small Cell Lung Cancer:** Guidelines (version 3.2023 – April 13, 2023) recommend Tafinlar + Mekinist® (trametinib tablets) for first-line "preferred" and subsequent therapy (both category 2A) for *BRAF V600E* mutation-positive disease.[6] Zelboraf or Tafinlar monotherapy is also recommended under "useful in certain circumstances" (both category 2A). Braftovi + Mektovi combination is not yet addressed in the guidelines.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Braftovi. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Braftovi is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Colon or Rectal Cancer.** Approve for 1 year if the patient meets the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has *BRAF V600E* mutation-positive disease; AND
   - **C)** Patient has previously received a chemotherapy regimen for colon or rectal cancer; AND
     Note: Examples of chemotherapy regimens include a fluoropyrimidine such as 5-fluorouracil (5-FU), capecitabine; oxaliplatin, irinotecan, or an adjunctive chemotherapy regimen such as FOLFOX (5-FU, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin).
   - **D)** The medication is prescribed as part of a combination regimen for colon or rectal cancer.
     Note: Examples of combination regimens include Braftovi + Erbitux (cetuximab intravenous infusion), Braftovi + Vectibix (panitumumab intravenous infusion).

2. **Melanoma.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has unresectable, advanced, or metastatic melanoma; AND
   - **C)** Patient has *BRAF V600* mutation-positive disease.

3. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has *BRAF V600E* mutation-positive metastatic disease; AND
   - **C)** The medication will be taken in combination with Mektovi (binimetinib tablets).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Braftovi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Braftovi® capsules [prescribing information]. Boulder, CO: Array BioPharma; October 2023.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (version 2.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on July 10, 2023.
3. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on July 10, 2023.
4. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – May 26, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on July 10, 2023.
5. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 10, 2023. Search terms: encorafenib.
6. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – April 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on October 16, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date

Annual Revision	No criteria changes.	08/03/2022
Annual Revision	No criteria changes	07/19/2023
Selected Revision	**Non-Small Cell Lung Cancer:** Added new FDA-approved indication and criteria	10/18/2023